

### Remarks

Claims 47-50, 55-58, 82 and 83 currently are pending and stand rejected. The Office is maintaining the following grounds of rejection.

Claims 47-50, 55-58, 82 and 83 are rejected under 35 U.S.C. §112, first paragraph as not supported by adequate written description. The Office Action refers to claims amended to recite that "the peptide or peptide derivative must be no more than 25 amino acid residues in length and 'comprises' a peptide of 10 contiguous amino acid residues of a selected GAD peptide." The Office asserts that the claimed peptides "require a 'core' of at least 10 contiguous amino acid residues" and that the claims use the open language "comprising," which permits inclusion of up to 15 undisclosed amino acids, resulting in nearly  $7.6 \times 10^{24}$  claimed but undisclosed peptides.

Applicants respectfully submit that the Office has misinterpreted the claims which are pending. The independent claims (82 and 83) do not contain the quoted language and are drawn to an isolated complex which comprises a peptide or peptide derivative. This peptide or peptide derivative is selected from the group consisting of named sequences or fragments thereof. The fragments of these named sequences have at least 6 contiguous amino acids of the named sequences. There are no unspecified flanking sequences or any undisclosed amino acid sequences in the SEQ ID NOS required by the claims.

The claims pending currently and which were pending on October 20, 2004 do not refer to a core of at least 10 contiguous amino acids or to a peptide of up to 25 amino acids. Claim 46, which includes this type of language had been canceled in a previously filed response. Claims 82 and 83, examined here, also do not contain the language quoted in the Office Action, page 3, lines 8-13. Applicants therefore respectfully submit that the

reasons outlined for the maintenance of this rejection do not apply to the claims under examination at this time.

In claims 82 and 83, the claimed complex comprises a peptide or peptide derivative. This open language does not relate to the sequences which are included in the phrase "peptide or peptide derivative." The phrase "peptide or peptide derivative," which is focused on by the Office, is limited by the language in the "wherein" clause below. The peptides claimed in claim 82 are SEQ ID NO: 2, 3 or 19-39. The fragments claimed in claim 82 are fragments of these specific, named sequences which have at least 6 contiguous amino acids of these specific, named sequences. The Office already has stated that the specification supports these peptides and fragments.

The claimed fragments are of a limited class. All members of this class are fragments of the named sequences, and the exact sequence of each numbered peptide is provided in the specification. Therefore all possible fragments claimed contain only sequences of the specific, named sequences. Other, "undisclosed" amino acids are not claimed--only sequences that are fragments of SEQ ID NOS: 2, 3 or 19-39 are claimed. Further, the fragments "have" at least 6 contiguous amino acids of these sequences. The term "have" is open language, but since the claimed fragments must be fragments of the named sequences, the claimed peptides and fragments of them are specific, named, and fully described under the standards of 35 U.S.C. §112, first paragraph. No unidentified amino acid sequences are encompassed by this claim. Claim 83 is further limited to peptides and peptide derivatives that are at least 12 contiguous amino acids of the specific, named sequence. Although this claim uses the term "is," it is not open with respect to the sequences of the peptides/derivatives.

The Office has conceded that the specification does provide descriptive support of the specific GAD segments named in the claims and contiguous fragments thereof. Applicants respectfully submit that this is what is claimed in claims 82 and 83 and therefore that the claims are allowable.

The Office Action responds to previously made arguments by focusing on the phrase "peptide derivatives" in claims 82 and 83, implying that this phrase is the reason why the previous rejection is maintained as argued above. Applicants submit that the phrase "peptide derivatives" does not relate in any way to the sequences of the peptides and fragments which are claimed.

Applicants direct the Office's attention to the original specification at page 8, line 27 to page 9, line 17. Here, the phrase "peptide derivatives" is defined. Applicants submit that it is clear to the skilled artisan, upon reading the specification, that this language as used in this application does not refer to additional or different flanking amino acids as the Office is assuming, but to chemical derivatives of the amino acids that are recited. This term does not include non-recited amino acid sequences. It refers to peptides of known sequence in which one or several amino acids have been derivatized by chemical reaction or which are a naturally occurring homolog. In the cited text in the original specification, Applicants have provided a detailed description of the term and several examples. Applicants submit that no skilled person would interpret this description to include sequence "derivatives" between 10 and 25 amino acids in length but with undisclosed sequence.

Skilled artisans are intimately familiar with chemical derivatization of reactive amino, carboxyl, hydroxyl groups and the like of amino acids and of the well-known homologs of the standard 20 amino acids. The chemical structures of these compounds are known to any biochemist. Therefore, no skilled

person would doubt that Applicants had possession of the limited number of sequences encompassed by SEQ ID NOS:2, 3, 19-39 and fragments thereof, and derivatives thereof. Claims must be interpreted in light of the specification. Applicants submit that the claim language is clear, defined and fully supported by the specification.

Claims 82 and 83 are amended in this response to add the phrase "or peptide derivative" to the final clause. This amendment is made to clarify that the peptide derivatives as well as the peptides (non-derivatized) are limited by this clause. No change in scope is intended by this amendment.

Applicants request, for the reasons discussed above, that the Office withdraw the rejection of the claims on grounds of lack of written descriptions.

Claims 47-50, 55-58, and 82-83 are rejected under 35 U.S.C. §112, first paragraph as not enabled by the specification. The bases for this rejection are essentially the same as those discussed above with respect to written description. Here, the Office has conceded that the specification does enable a complex comprising a peptide or peptide derivative of GAD which consists of at least 6 peptide contiguous amino acids of the sequences recited in the claims. The claims are limited to peptides (and derivatives) selected from the recited sequences and fragments of these sequences. All of these sequences are specific, named and disclosed in the specification. All fragments of SEQ ID NOS: 2, 3 and 19-39 are disclosed in the specification, and would have been easily accessible to the skilled artisan reading this claim.

The claims do not encompass any sequences with unknown, unnamed amino acid sequences or  $7.6 \times 10^{24}$  different peptide sequences. The peptides covered by the claims are SEQ ID NOS: 2, 3 and 19-39 and fragments of these named sequences; not 10-mers with additional undisclosed flanking amino acid sequences not

part of SEQ ID NOS: 2, 3 and 19-39. All peptides and fragments thereof encompassed by the claims under examination have contain only sequences contained in SEQ ID NOS: 2, 3 and 19-39.

Therefore the Office's reasoning with respect to the asserted scope of the claims is not correct and is at least partially based on language quoted in the Office Action (see above) but not contained in the claims.

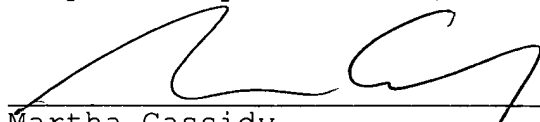
The Office again refers to the phrase "peptide derivatives" in claims 82 and 83. Applicants refer the Office to the discussion above with respect to the definition of that phrase in the specification. The term "derivatives" is not understood by the skilled person who reads the specification to refer to unnamed sequences of amino acids but to chemically derivatized amino acids within the specific named sequence.

For the reasons discussed above, Applicants respectfully submit that the rejection of these claims as not enabled is not proper and is based on a misinterpretation of the claims.

Applicants request that the Office reconsider the claim language which is pending and refer to the specification as filed for its interpretation as required. Applicants respectfully submit that the claims should be allowed at this stage.

Respectfully submitted,

By



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